ATTENTION PHARMACISTS

THE 1ST FDA-APPROVED
orally administered levothyroxine sodium treatment for hypothyroidism[1,2]

UNITHROID

A TREATMENT FOR HYPOTHYROIDISM THAT'S THERE AT EVERY TURN

BRAND CONSISTENCY

Tablet shown not actual size.

NO HISTORY OF RECALLS OR REFORMULATIONS

UNITHROID has been manufactured for more than 20 years with no recalls, reformulations, or gaps in availability.[3]

DISPENSE AS WRITTEN

If a doctor wants a patient to receive UNITHROID, he or she will write "Dispense as Written" (or DAW*) on the prescription. This means substitutions are not permitted. Using DAW provides assurance that patients consistently receive the same levothyroxine preparation with every refill instead of various generic substitutes.

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS GUIDELINES

Because levothyroxine has a narrow therapeutic range, small differences in absorption can result in subclinical or clinical hypothyroidism or hyperthyroidism.[4]

*Or alternative language required by your state.

QUALITY

UNITHROID tablets have been manufactured in the same US facility for more than 2 decades.[3]

UNITHROID contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).[3]

AFFORDABILITY

Eligible patients may pay as little as

$3 FOR A 30-DAY UNITHROID PRESCRIPTION†

†See Eligibility Criteria and Terms and Conditions at UNITHROIDHCP.com/TandC.

See other side for **UNITHROID** ordering information

To learn more, turn to UNITHROIDHCP.com/Pharmacy.

INDICATION

UNITHROID is L-thyroxine (T4) indicated in pediatric and adult patients for:

- Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer

Limitations of Use:

UNITHROID is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with UNITHROID may induce hyperthyroidism. UNITHROID is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including UNITHROID, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

Contraindication

UNITHROID is contraindicated in patients with uncorrected adrenal insufficiency.

Warnings and Precautions

- Overtreatment with UNITHROID may cause an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias particularly in patients with cardiovascular disease and in elderly patients. Initiate UNITHROID therapy at lower doses than those recommended in younger individuals or in patients without cardiac disease.

Please see additional Important Safety Information on the back and full Prescribing Information.

UNITHROID IS AVAILABLE IN 12 STRENGTHS[1]

Contact your wholesaler to order **UNITHROID**

Strength (mcg)		NDC	AmerisourceBergen	Cardinal Health	McKesson
Peach	25	60846-0801-01	10141149	4999314	3421427
White	50	60846-0802-01	10141170	4999330	3421690
Purple	75	60846-0803-01	10141171	4999348	3422870
Olive	88	60846-0804-01	10141172	4999405	3423001
Yellow	100	60846-0805-01	10141173	4999413	3423829
Rose	112	60846-0806-01	10141174	4999421	3423092
Tan	125	60846-0807-01	10141175	4999447	3423100
Blue	137	60846-0808-01	10141176	4999454	3425378
Light Blue	150	60846-0809-01	10141177	4999272	3423183
Lilac	175	60846-0810-01	10141178	4999256	3423738
Pink	200	60846-0811-01	10141179	4999249	3424447
Green	300	60846-0812-01	10141180	4999223	3424900

Tablets shown not actual size.

IMPORTANT SAFETY INFORMATION (*continued*)

Warnings and Precautions (*continued*)

- Coronary artery disease: Patients receiving UNITHROID should be monitored closely during surgical procedures for cardiac arrhythmias. Also, monitor patients during concomitant administration of UNITHROID and sympathomimetic agents for signs and symptoms of coronary insufficiency.
- Myxedema coma: is a life-threatening emergency characterized by poor circulation and hypometabolism, and may result in unpredictable absorption of UNITHROID from the gastrointestinal tract. Use of oral thyroid hormone drug products is not recommended. Administer intravenous thyroid hormone products to treat myxedema coma.
- Acute adrenal crisis in patients with concomitant adrenal insufficiency: thyroid hormone increases metabolic clearance of glucocorticoids. Initiation of thyroid hormone therapy prior to initiating glucocorticoid therapy may precipitate an acute adrenal crisis in patients with adrenal insufficiency.
- UNITHROID has a narrow therapeutic index. Titrate the dose of UNITHROID carefully and monitor response to titration to avoid effects of over or under treatment with UNITHROID. Monitor for the presence of drug or food interactions when using UNITHROID and adjust the dose as necessary.
- Addition of levothyroxine therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing UNITHROID.
- Increased bone resorption and decreased bone mineral density may occur as a result of levothyroxine over-replacement, particularly in post-menopausal women. To minimize this risk, administer the minimum dose of UNITHROID that achieves the desired clinical and biochemical response.

Adverse Reactions

- Common adverse reactions for UNITHROID are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.
- Pediatric Patients: Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in pediatric patients receiving levothyroxine therapy Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in pediatric patients with resultant compromised adult height.

Drug Interactions

- Many drugs can exert effects on thyroid hormone pharmacokinetics and may alter the therapeutic response to UNITHROID. Administer at least 4 hours before or after drugs that are known to interfere with absorption. Consumption of certain foods may affect absorption of UNITHROID, resulting in the need for dose adjustment. Consult appropriate sources of information on drug or food interactions for additional information relative to drug or food interactions with UNITHROID.
- Drug-Laboratory test interactions: Consider changes in TBG concentration when interpreting T4 and T3 values. Measure and evaluate unbound (free) hormone and/or determine the free T4 index (FT4I) in this circumstance.

Use in Specific Populations

- Pregnancy: Since thyroid-stimulating hormone (TSH) levels may increase during pregnancy, TSH should be monitored and UNITHROID dosage adjusted during pregnancy. UNITHROID should not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information, including Boxed Warning, on the front and full Prescribing Information.

References: 1. UNITHROID [package insert]. **2.** US Food and Drug Administration. Guidance for Industry: levothyroxine sodium products enforcement of August 14, 2001, compliance date and submission of new applications. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/levothyroxine-sodium-products-enforcement-august-14-2001-compliance-date-and-submission-new. Updated July 2001. Accessed May 4, 2020. **3.** Data on file. Amneal Pharmaceuticals LLC. **4.** Baskin HJ, Cobin RH, Duick DS, et al; for American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hyperthyroidism and hypothyroidism. *Endocr Pract*. 2002;8(6):457-469.

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UNITHROID®
(Levothyroxine Sodium Tablets, USP)

A STEP BEYOND